May 16, 2019

Siemens Healthcare GmbH
% Mr. Georg Bauer
Responsible Third-Party Official
TÜV SÜD America, Inc.
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112

Re: K191040
Trade/Device Name: syngo.via (Version VB40A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 17, 2019
Received: April 19, 2019

Dear Mr. Bauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191040

Device Name
syngo.via (Version VB40A)

Indications for Use *(Describe)*
syngo.via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images.
It can be used as a stand-alone device or together with a variety of cleared and unmodified syngo based software options. syngo .via supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.
The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Date prepared: April 03, 2019

1. **Submitter:**
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   Establishment Registration Number:
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3. **Device Name and Classification:**

Trade Name:	*syngo*.via (Version VB40A)
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ

4. **Legally Marketed Predicate Device:**

Trade Name:	*syngo*.via (Version VB10A)
510(k) Clearance:	K150843
Clearance Date:	April 25, 2015
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ
Recall Information:	This predicate device has not been the subject of any design related recalls.

5. Device Description:

Siemens Healthcare GmbH intends to market the Picture Archiving and Communications System, *syngo*.via, software version VB40A. This 510(k) submission describes several modifications to the previously cleared predicate device, *syngo*.via, software version VB10A.

syngo.via is a software only medical device, which is delivered by download to be installed on common IT hardware. This hardware has to fulfil the defined requirements. Any hardware platform that complies to the specified minimum hardware and software requirements and with successful installation verification and validation activities can be supported. The hardware itself is not seen as part of the medical device *syngo*.via and therefore not in the scope of this 510(k) submission.

syngo.via provides tools and features to cover the radiological tasks *reading images* and *reporting*. *syngo*.via supports DICOM formatted images and objects. *syngo*.via also supports storage of Structured DICOM Reports. In a comprehensive imaging suite, *syngo*.via interoperates with a Radiology Information System (RIS) to enable customer specific workflows.

syngo.via is based on a client-server architecture. The server processes and renders the data from the connected modalities. The server provides central services including image processing and temporary storage, and incorporates the local database. The client provides the user interface for interactive image viewing and processing and can be installed and started on each workplace that has a network connection to the server.

The server's backend communication and storage solution is based on Microsoft Windows server operating systems. The client machines are based on Microsoft Windows operating systems.

syngo.via supports various monitor setups and can be adapted to a range of image types by connecting different monitor types.

The subject device and the predicate device share the same fundamental scientific technology. This device description holds true for the subject device, *syngo*.via, software version VB40A, as well as the predicate device, *syngo*.via, software version VB10A.

6. Intended Use:

*syngo.*via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images.
It can be used as a stand-alone device or together with a variety of cleared and unmodified *syngo* based software options.

*syngo.*via supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.

The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

7. Summary of Differences between the Subject Device and the Predicate Device:

The differences between the subject device described in this premarket notification and the predicate device are summarized in the following comparison table:

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
Device name and version (K number)	***syngo*.via (Version VB40A)**	***syngo*.via *(*Version VB10A) (K150843)**	New product version	NA
Manufacturer	Siemens Healthcare GmbH	Siemens AG Medical Solutions	Legal manufacturer change[22].	NA
Intended use	*syngo.via* is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a stand-alone device or together with a variety of cleared and unmodified *syngo* based software options. *syngo.via* supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments. The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.	*syngo.via* is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a stand-alone device or together with a variety of cleared and unmodified *syngo* based software options. *syngo.via* supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments. The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.	Same	NA

[22] *syngo*.via VB10A was manufactured by Siemens AG Medical Solutions during the time of its filing. Later-on legal manufacturer change was performed to Siemens Healthcare GmbH. So finally, the legal manufacturer is identical for both devices.

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
Software architecture	Client-server architecture that is logically broken down to *syngo.via* subsystems. Subsystems are further broken down to *syngo* modules.	Client-server architecture that is logically broken down to *syngo.via* subsystems. Subsystems are further broken down to *syngo* modules.	Same	NA
Image communication	Standard network protocols like TCP/IP and standard communication protocol DICOM. Additional fast image transfer protocol for use inside *syngo*.via between the client and server.	Standard network protocols like TCP/IP and standard communication protocol DICOM. Additional fast image transfer protocol for use inside *syngo*.via between the client and server.	Same	NA
Imaging algorithms	- Multiplanar reconstruction (MPR) - Maximum and Minimum Intensity Projection (MIP/MinIP) - Volume Rendering Technique (VRT) with additional technique Cinematic VRT for photorealistic rendering - Shaded Surface Display (SSD) - Editor functionality (e.g. ClipBox) - Registration - Anatomical registration - Region growing with single click region growing - Organ segmentation based on existing ALPHA technology. - Change Visualization - Automatic Spine Labeling, also for ribs in CT thorax scans[13] ("Rib labeling")	- Multiplanar reconstruction (MPR) - Maximum and Minimum Intensity Projection (MIP/MinIP) - Volume Rendering Technique (VRT) - Shaded Surface Display (SSD) - Editor functionality (e.g. ClipBox) - Registration - Anatomical registration - Region growing - Automatic Spine Labeling, also for ribs in CT thorax scans[23] ("Rib labeling")	There are enhancements to the existing algorithms in the subject device compared to the predicate device. cVRT: Cinematic VRT is an extension to the standard VRT rendering algorithm to visualize the photorealistic images. Organ Segmentation: Organ Segmentation is an enhancement based on the existing but improved ALPHA technology to visualize the anatomical regions Heart, Lung and Aorta. Change Visualization: This algorithm helps to visualize the anatomical changes	The changes between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary measures taken for the safety and effectiveness of the subject device.

[23] Rib Labeling as a functionality was already covered by a 510(k) clearance with device *syngo*.CT Bone Reading, K123584.

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
			in the lung region between two series belonging to different time points.	
Quantitative algorithms	Distance and angle measurements	Distance and angle measurements	Same	NA
Supported Image Generating Modalities	The following Image types are supported by syngo.via: - CT Image (Computed Tomography) - MR Image (Magnetic Resonance) - NM Image (Nuclear Medicine) - XA Image (X-Ray Angiography) - US Image (Ultrasound) - DX Image (Digital Radiography) - DICOM secondary capture objects	The following Image types are supported by syngo.via: - CT Image (Computed Tomography) - MR Image (Magnetic Resonance) - NM Image (Nuclear Medicine) - XA Image (X-Ray Angiography) - US Image (Ultrasound) - DX Image (Digital Radiography) - DICOM secondary capture objects	Same	NA
Image data Compression	Receive & Store: Images are received and stored as received without any change in the compression format. Display: The images are displayed as received without any change in the compression. Lossy compression images are displayed with an indication to the user with the compression ratio. Export: To DICOM node and Exchangeable media: Images are sent as per the DI-	Receive & Store: Images are received and stored as received without any change in the compression format. Display: The images are displayed as received without any change in the compression. Lossy compression images are displayed with an indication to the user with the compression ratio. Export: To DICOM node and Exchangeable media: Images are sent as per the DI-	Same	NA

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
	COM negotiation and depending on Compression settings. Lossy compression is not supported. Supported Compressions for export: lossless compression algorithms, JPEG, JPEG 2000 and RLE.	COM negotiation and depending on Compression settings. Lossy compression is not supported. Supported Compressions for export: lossless compression algorithms, JPEG, JPEG 2000 and RLE.		
Operating system	Client: Microsoft Windows 7 SP1 or Microsoft Windows 8.1 or Microsoft Windows 10 Server: Microsoft Windows Server 2008 R2 or Microsoft Windows Server 2012 R2. or Microsoft Server 2016	Client: Microsoft Windows 7 SP1 or Microsoft Windows 8.1 Server: Microsoft Windows Server 2008 R2 or Microsoft Windows Server 2012 R2	In the subject device client supports the Microsoft Windows 10 Operating system and Server supports Microsoft Windows Server 2016 additionally compared to the predicate device.	This Operating System difference between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary measures taken for the safety and effectiveness of the subject device.
Impact on Image Generating Devices	None *syngo*.via is a pure post processing software and no influence on the image generating devices.	None *syngo*.via is a pure post processing software and no influence on the image generating devices.	NA as both the devices do not impact the Image generating devices.	NA
CAD Functionalities	None. No automated diagnostic interpretation capabilities like CAD are included. All image data are to be interpreted by trained personnel. Note: The LungCAD Navigation Tool provides the user interface to visualize the results of the external LungCAD algorithm which is cleared with syngo.CT LungCAD as an accessory (K143196).	None. No automated diagnostic interpretation capabilities like CAD are included. All image data are to be interpreted by trained personnel.	NA as both the devices don't support any CAD functionalities. Note for Subject device: The LungCAD Navigation tool doesn't provide any CAD Functionality rather only provides the user interface to view the results generated by external LungCAD algorithm.	NA

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
Software self-test / checks	Indicates the user in case that data coming from an interface cannot be assigned to a task flow to assign it manually. In case of a data mismatch due to incorrect or inconsistent use of DICOM rules the administrator can change the data transfer protocol and patient identification rules (DICOM Parser Tool). When the audit trail folder exceeds the configured level of storage, a warning message is sent to the administrator by e-mail, if configured. Client installation is prevented automatically in case if the system doesn't have the recommended operating system. Also during the launch of the client every time, the compatibility to the server version is checked and request to update/upgrade to client in case of mismatch. Database recovery tool restores the data if the integrity checks between the Short term Storage and syngo.via database fails. A new instance of DICOM object is created in case of any non-reversible modification is performed on the DICOM Object (e.g. Lossy compression, reduction of color depth,	Indicates the user in case that data coming from an interface cannot be assigned to a task flow to assign it manually. In case of a data mismatch due to incorrect or inconsistent use of DICOM rules the administrator can change the data transfer protocol and patient identification rules (DICOM Parser Tool). When the audit trail folder exceeds the configured level of storage, a warning message is sent to the administrator by e-mail, if configured. Client installation is prevented automatically in case if the system doesn't have the recommended operating system. Also during the launch of the client every time, the compatibility to the server version is checked and request to update/upgrade to client in case of mismatch. Database recovery tool restores the data if the integrity checks between the Short term Storage and syngo.via database fails. A new instance of DICOM object is created in case of any non-reversible modification is performed on the DICOM Object (e.g. Lossy compression, reduction of color depth,	Same	NA

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
	resampling of image matrix, etc.)	resampling of image matrix, etc.)		
Cyber Security	- User access control - Audit trails - Documentation of system security information, Network traffic & Firewall control - Support of virus / malware protection. - System Hardening - Device guard	- User access control - Audit trails - Documentation of system security information, Network traffic & Firewall control - Support of virus / malware protection.	The security of the system was increased over the years by introducing the System Hardening and the Device Guard.	The new security functions don't impact the safety and effectiveness of the subject device as the necessary measures taken for the safety and effectiveness of the subject device.
Hardware	Hardware is not understood as part of the medical device, but needs to comply with the minimum requirements as specified by *syngo*.via.	Hardware is not understood as part of the medical device, but needs to comply with the minimum requirements as specified by *syngo.via*.	Same	NA
Software functionalities				
Workflow control	Workflows support the user in preparing images for examination. Based on information such as modality and body part, *syngo.via* assigns workflows to studies.	Workflows support the user in preparing images for examination. Based on information such as modality and body part, *syngo.via* assigns workflows to studies.	Same	NA
Graphical user interface	Yes, with reduced color palette, clearer structure and text labels on icons. Floating panels increases the user friendliness as the user can move the panels wherever they are convenient with.	Yes, with reduced color palette, clearer structure and text labels on icons	In compared to the predicate device, the subject device has the option to move certain panels (e.g. Favorite Tools) wherever he/she wants to. This gives greater flexibility to the user.	This difference between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary measures taken for the safety and effectiveness of the subject device.

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
Image text	Yes, with Interactive Image text and configurable settings.	Yes, with additional configurable settings.	In the subject device there is an additional functionality that the selective image texts can be manipulated with mouse click and scroll.	This difference between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary measures taken for the safety and effectiveness of the subject device.
Patient Browser	Yes, with simplified search functionality, clearer structure of search results, unlimited search results, periodic updates of search results, image preview and flexible floating patient browser window.	Yes, with simplified search functionality, clearer structure of search results, unlimited search results, periodic updates of search results, image preview and flexible floating patient browser window.	Same.	This difference between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary measures taken for the safety and effectiveness of the subject device.
Series navigator	Yes, the Series Navigator lists all currently loaded data within a workflow. Series Navigator supports the Thumbnail view and switching between Preview, List and Thumbnail views for both series and instances level.	Yes, the Series Navigator lists all currently loaded data within a workflow.	The subject device supports the Thumbnail views for Series and Instances and the user can switch between the List, Preview and Thumbnail views.	NA
Findings navigator / Findings Assistant	Yes, Findings Assistant lists all measurements, graphical objects, annotations, and snapshots. Additionally the user can create new findings, edit findings, trend findings over time,	The Findings Navigator lists all measurements, graphical objects, annotations, and snapshots.	Findings Navigator from the predicate device is renamed with Findings Assistant with the improvements like create findings, edit findings,	This difference between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
	cluster findings based on body region.		findings trending, and cluster findings.	measures taken for the safety and effectiveness of the subject device.
Reporting	Yes, with functionality to create one page reports, insert snapshot images, customize reports, and data export in various formats. Also with edit option of the attributes of findings in the report editor & trend findings over time. The automation of the supported guidelines is filled on its own for easy reference of the user. The integration of the findings export with Nuance Powerscribe 360 is enabled.	Yes, with functionality to create one page reports, insert snapshot images, customize reports, and data export in various formats.	There are some minor improvements to the existing reporting functionality like standard guideline automation based on user entries, interfacing with external reporting applications, findings trending.	This difference between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary measures taken for the safety and effectiveness of the subject device.
Correct and rearrange	Yes, for administrative users, correction capabilities and rearranging of data are added.	Yes, for administrative users, correction capabilities and rearranging of data are added.	Same	NA
Import and export of data	Import of DICOM data from network nodes or external media, and of DICOM-compliant or non DICOM-compliant data from external media and Windows file system. Export to CD/DVD, Windows file system, or other DICOM nodes.	Import of DICOM data from network nodes or external media, and of DICOM-compliant or non DICOM-compliant data from external media and Windows file system. Export to CD/DVD, Windows file system, or other DICOM nodes.	Same	NA
Archiving data	Data can be sent to an archive if *syngo*.via is connected to a PACS or corresponding DICOM node.	Data can be sent to an archive if *syngo*.via is connected to a PACS or corresponding DICOM node.	Same	NA
Ranges	Yes, parallel, radial, Radial sliced, Curved and Spine ranges are support-	Yes, parallel, radial, Radial sliced, Curved and Spine ranges are support-	Same	NA

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
	ed. Additionally supported all the Ranges with anatomical range presets for CT and MR images.	ed. Additionally supported all the Ranges with anatomical range presets for CT and MR images.		
Spine/Rib labeling	Yes, with suggested spine labels to be confirmed by the user, and additional smart placement of labels, also in inter-vertebra regions, support of 2D images, support of multi-series studies, and added support for rib labels.	Yes, with suggested spine labels to be confirmed by the user, and additional smart placement of labels, also in inter-vertebra regions, support of 2D images, support of multi-series studies, and added support for rib labels.	Same	NA
Communication	Yes, Interface with DICOM, HL7 is possible.	Yes, Interface with DICOM, HL7 is possible.	Same	NA
Printing	Yes, with support to print image text, apply same zoom factor for all selected images and selection of DICOM printer or paper printer. Also the direct printing from Patient browser is possible now and the administrator can configure a default printer for the client instead of user.	Yes, with support to print image text and selection of DICOM printer or paper printer.	The improvements include the interactive zoom, direct printing from Patient browser and local printer configuration in clients.	This difference between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary measures taken for the safety and effectiveness of the subject device.
Online help system	Yes, with search, indexing, filtering, library function, document collections, and user-generated content.	Yes, with search, indexing, filtering, library function, document collections, and user-generated content.	Same	NA
Markers and annotations	Yes, - with support for marking a position on an image and textual an-	Yes, - with support for marking a position on an image and textual an-	Same	NA

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
	notations. - with added textual and graphical annotations, improved placement of measurement text, and changed numbering of markers.	notations. - with added textual and graphical annotations, improved placement of measurement text, and changed numbering of markers.		

8. Non-clinical Performance Testing:

Non-clinical tests were conducted for the device *syngo*.via during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

Siemens Healthcare GmbH claims conformance to the following standards:

- NEMA PS 3.1 – 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set
- ISO/IEC 10918-1 First edition 1994-02-15 + Technical Corrigendum 1 (2005) (JPEG)
- ISO/IEC 15444-1:2016 (JPEG2000)
- ISO 14971 Second edition 2007-03-01
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION
- IEC 82304-1 Edition 1.0 2016-10
- IEC 62366-1 Edition 1.0 2015-02
- IEEE Std 3333.2.1-2015
- ISO/HL7 21731:2014 (Version 2.x)

Software Verification and Validation:

Software documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests were conducted on the device *syngo*.via during product development.

The Risk Analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

Siemens Healthcare GmbH conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Contained in Section B of this submission are our cybersecurity considerations as they relate to the device *syngo*.via.

Summary:
Performance tests were conducted to test the functionality of the device *syngo*.via. These tests have been performed to assess the functionality of the subject device. Results of all conducted testing were found acceptable in supporting the claim of substantial equivalence.

9. Safety and Effectiveness Information:

Software specifications, design descriptions, hazard analysis, and labeling information are submitted in support of this premarket notification. The device labeling contains instructions for use with cautions to provide for safe and effective use of the device.

The results of the hazard analysis combined with the appropriate preventive measures taken indicate the device is of moderate level of concern, as per the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

10. Conclusion as to Substantial Equivalence:

The predicate device was cleared based on non-clinical supportive information. The comparison of technological characteristics, device hazards, non-clinical performance data, and software validation data demonstrates that the subject device performs comparably to and is as safe and effective as the predicate device that is currently marketed for the same intended use.

In summary, we are of the opinion that the subject device *syngo*.via, software version VB40A, does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate device.